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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,244	10/23/2003	Thomas E. Cross JR.	P-10991.00US	8397

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MEDTRONIC, INC.
710 MEDTRONIC PARK
MINNEAPOLIS, MN 55432-9924

EXAMINER

JACKSON, BRYAN M

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/692,244	CROSS, THOMAS E.	
	Examiner	Art Unit	
	Bryan M. Jackson	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/23/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35, 39-42 and 45-55 is/are rejected.
- 7) ☒ Claim(s) 36-38, 43 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/11/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The Information disclosure statement (IDS) submitted on 1/11/05 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claim 46 and Figure 9 (Drawings) are objected to because of the following informalities:

As to figure 9, it is unclear as to where the structure 69, a 'butt joint', is displayed.

As to claim 46, it is unclear on line 3 whether or not the Applicant wishes to claim "an n open position", it is considered to be a typo and it is suggested to change to "an open position."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 24-26, "clamping arms" lacks antecedent basis, it suggested to change "clamping arms" to "clamping jaws."

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 12, and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Rezai et al. (20050131506).

Rezai et al. discloses a tubular lead body (fig 7, 715), a connector on the proximal end of a lead body (fig 7, 725), four in-line electrodes located on an elongate paddle at the distal end of the lead (pg 1, para 8), aperture (fig 8A, 855) for a plurality of electrodes, wherein the aperture is capable of performing the function of the applicant's apertures, conductors (fig 2A, 255) are welded to the distal ends of electrodes (fig 2A, 240) to provide strain relief (pg 3, para 39).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7, 13, 15-21, and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rezai et al. (20050131506).

As to claim 7, Rezai et al. discloses the claimed invention but does not disclose expressly the butt joint. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the implanted flat paddle connected to a tubular lead body, as taught by Rezai et al., with the a butt joint, because Applicant has not disclosed that a butt joint provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the implanted flat paddle connected to a tubular lead body as taught by Rezai et al., because it provides a power source and electrical stimulation therapy to a patient, and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Rezai et al.

Therefore, it would have been an obvious matter of design choice to modify Rezai et al. to obtain the invention as specified in the claim(s).

As to claim 13, two flat portions being assembled together is a process used to form the product of a flat paddle. The process of assembling two flat portions together to form a flat paddle can also be used to assemble devices such as a housing of an Implantable Pulse Generator (IPG).

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As to claim 15, the butt bonding of two sections together is a process used to form the product of a flat paddle. The process of butt bonding of two sections together to form a flat paddle can also be used to form devices such as a housing of an Implantable Pulse Generator (IPG).

As to claims 16-17, Rezai et al. discloses the claimed invention but does not disclose expressly the offset butt bonds extending generally across the width of the paddle. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the flat paddle of Rezai et al., with the offset butt bonds extending generally across the width of the paddle, because Applicant has not disclosed that offset butt bonds extending generally across the width of the paddle provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the flat paddle of Rezai et al., because it provides a means for reducing the movement of electrical components implanted within a biological organism, and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Rezai et al.

Therefore, it would have been an obvious matter of design choice to modify Rezai et al. to obtain the invention as specified in the claim(s).

As to claims 18-21 and 30-33, Rezai et al. discloses the claimed invention but does not disclose expressly the electrode array of length at least 1-1/2 to at least 4 inches. It would have been an obvious matter of design choice to a

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person of ordinary skill in the art to modify the electrode array of Rezai et al., with the electrode array of length at least 1-1/2 to at least 4 inches, because Applicant has not disclosed that the electrode array of length at least 1-1/2 to at least 4 inches provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the electrode array of Rezai et al., because it provides an electrical contact with a nerve surface, and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Rezai et al.

Therefore, it would have been an obvious matter of design choice to modify Rezai et al. to obtain the invention as specified in the claim(s).

Claims 4 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rezai et al. in view of Erickson et al. (6895283).

Rezai et al. discloses the claimed invention except for the at least eight electrodes (claim 4). Erickson et al. teaches that it is known to use eight electrodes (fig 1) in the same field of neurostimulation to increase the area of electrical contact between a device and a nerve surface. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device Rezai et al., with eight electrodes, as taught by Erickson et al., in order to provide an increased neurostimulation area.

Rezai et al. discloses the claimed invention except for the polyurethane flat paddle (claim 29). Erickson et al. teaches that it is known to use a paddle

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structure of polyurethane material (col 5, ln 13-15) to reduce the probability of rejection by the human body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the flat paddle of Rezai et al., with a paddle structure of polyurethane material, as taught by Erickson et al., in order to enhance biocompatibility.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rezai et al. in view of Talalla et al. (4633889).

Rezai et al. discloses the claimed invention except for the recessed electrodes. Talalla et al. teaches that it is known to use recessed electrodes (col 6, ln 2-4) to prevent undesired direct contact of electrodes with nerve surfaces. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify device of Rezai et al., with recessed electrodes, as taught by Talalla et al., in order to prevent undesired direct contact of electrodes with nerve surfaces.

Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rezai et al. in view of Meadow et al. (6741892).

Rezai et al. discloses the claimed invention except for the plurality of ring contacts separated by insulating ring spacers. Meadow et al. teaches that it is known to use an insulated lead body with a plurality of lead contacts, considered to be ring-shaped connector (fig 2, 24), to provide an electrical connection between an IPG and an insulated lead body. It would have been obvious to one

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having ordinary skill in the art at the time the invention was made to modify the plug-in connector of Rezai et al., with the ring-shaped connector of Meadow et al., in order to provide an obvious exchanging of functionally equivalent connectors.

Rezai et al. and Meadow et al. disclose the claimed invention but does not disclose expressly the laser weld (claim 11). It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the ring contacts connected to conductors of a lead body via a weld, as taught by Rezai et al. and Meadow et al., with the a laser weld, because Applicant has not disclosed that a laser weld provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with a plurality of ring contacts welded to conductors of a lead body, as taught by Rezai et al. and Meadow et al., because it provides an electrical connection between the IPG and insulated lead body for delivering electrical stimulation therapy to a patient, and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Rezai et al. and Meadow et al.

Therefore, it would have been an obvious matter of design choice to modify Rezai et al. and Meadow et al. to obtain the invention as specified in the claim(s).

Claims 14 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rezai et al. in view of King (6745079).

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Rezai et al. discloses the claimed invention except for the passageway for a stylet. King teaches that it is known to use a strut including an open lumen (fig 6A, 49) as a passageway for a stylet (fig 7A, 18) to provide a means for positioning of a lead body in an epidural space. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rezai et al., with the use of an open lumen as a passageway for a stylet, as taught by King, in order to provide a means for orientation with respect to an implanted lead body.

Claims 22-23, 27, and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rezai et al. in view of Pohndorf et al. (5746722), Gerber (6055456), and Cabak et al. (20020082619).

Rezai et al. discloses the claimed invention except for the anchor and two clamping jaws. Pohndorf et al. teaches that it is known to use a suture sleeve for anchoring a structure to underlying tissue in the analogous art of implanted devices to provide a means for securing a structure to a patient's underlying tissue, wherein a ligamentum flavum is considered to be a type of underlying tissue. Gerber teaches that it is known to use an anchoring mechanism with suture holes (fig 2, 50) in the analogous art of neurostimulation for adhering an implanted stimulation lead with a conductive tip to the human body. Cabak et al. teaches that it is known to use fastener (fig 4 and 5) with two clamping jaws and sutures (fig 5, 42) for the reinforcing of an implanted medical device via two clamping jaws. Pohndorf et al., Gerber, and Cabak et al. do not explicitly state

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that the suture sleeve, anchoring mechanism, and fastener are used in conjunction with a flat paddle, but it appears that a suture sleeve, anchoring mechanism, and a fastener with clamping arms are used to provide a means for securing implanted neurostimulation devices to a patient's underlying tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rezai et al., with a suture sleeve, anchoring mechanism, and a fastener with clamping arms, as taught by Pohndorf et al., Gerber, and Cabak et al., since such a modification would provide the flat paddle with a means for adhering to a patient's underlying tissue.

Claims 40-42 and 45-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rezai et al., Pohndorf et al., Gerber, and Cabak et al. as applied to claim 34 above, and further in view of Hess (6233488).

Rezai et al., Pohndorf et al., Gerber, and Cabak et al. disclose the claimed invention except for the paddle through the ligamentum flavum into an epidural space through a needle. Hess teaches that it is known to use an epidural needle (fig 3a, 24) inserted between spinous processes and passing through ligamentum flavum (fig 3a, 26) into the epidural space (fig 3a, 27) to provide a means for orientating an electrical stimulator within a human body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the devices of Rezai et al., Pohndorf et al., Gerber, and Cabak et al., with an epidural needle inserted between spinous processes and passing through ligamentum flavum into the epidural space, as taught by Hess, in order

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to provide a means for orientating an electrical stimulator implanted within a human body.

Allowable Subject Matter

Claims 24-26, 36-38, and 43-44 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: "at least one rib" adapted to engage the flat paddle and retain it in position and a "plurality of ribs."

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Demopoulos (6080192) discloses a tendon and ligament repair system.

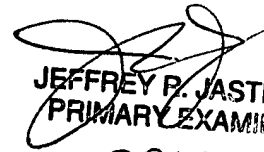
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bryan M. Jackson whose telephone number is 571-272-7335. The examiner can normally be reached on Monday through Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JEFFREY P. JASTRZAB
PRIMARY EXAMINER
3762
3/22/06